DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

SterilMed, Inc.
c/o Dr. Bruce R. Lester
Vice President of R & D
11400 73rd Avenue, North
Minneapolis, MN 55369

Re: K012574 - Supplemental Validation Submission
Trade/Device Name: Reprocessed Femoral Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Clamp, Vascular
Regulatory Class: II (2)
Product Code: NMF
Dated: April 30, 2002
Received: May 2, 2002

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on July 18, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120 (DOEB). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Attachment 1

USCI ® C.R. Bard®, Inc. / RADI Medical Systems AB
Model Number: 017500

OEM Trade Name: FemoStop® Femoral Compression System

Indications for use Page

Device Name: Reprocessed Femoral Compression Device

Indications for Use:

The reprocessed femoral compression device is intended for use in the compression of the femoral artery or vein after catheterization.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K012574

K02574

JUL 18 2002

SECTION 1. GENERAL INFORMATION

Submitter's Name	SterilMed, Inc.
Address	11400 73rd Avenue North, Minneapolis, MN 55369
Contact Person	Patrick Fleischhacker
Telephone	763-488-3400
Fax	763-488-3350
Date of Submission	August 7, 2001

a. **Proprietary Name:** Reprocessed Femoral Compression Device

b. **Common Name:** Femoral Compression Device

c. **Establishment Registration Number (ERN):** 2134070

d. **Classification Status:** Class II 21 CFR 870.4450

e. **Product Code:** DXC

f. **Addresses:**

Manufacturing / Distribution Facility:	Sterilization Facility Diffusion Method:	Sterilization Facility Chamber Method:
SterilMed, Inc. 11400 73rd Avenue North Minneapolis MN, 55369 ERN: 2134070	SterilMed, Inc. 11400 73rd Avenue North Minneapolis MN, 55369 ERN: 2134070 Or SterilMed Inc. 3650 Annapolis Lane North Suite 170 Minneapolis, MN 55447 ERN: 2134070	Steris Isomedix Services 380 90th Avenue NW, Minneapolis, MN 55433 ERN: 2183744

K012574

g. Reason for Submission:

To seek clearance to market reprocessed femoral compression devices that are substantially equivalent to other similar devices made by other manufacturers that are currently distributed in the United States.

h. Substantial Equivalence:

SterilMed, Inc. considers the reprocessed femoral compression device to be substantially equivalent to:

- The Femostop System® (K915280), manufactured by RADI Medical Systems

i. Performance Standards:

There are no specific standards promulgated by the FDA that apply to this product under Section 514 of the Act. However, SterilMed complied, wholly or in part, with several guidance documents and standards in preparation of this submission for their reprocessed femoral compression device and processes. These guidance documents and standards are listed in detail in Section 10 of this document.